



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,992	07/30/2003	Richard Waltz Harper	X-12086A	9150

25885 7590 05/28/2004

ELI LILLY AND COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER

ANDERSON, REBECCA L

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/629,992	Applicant(s) HARPER ET AL.	
	Examiner Rebecca L Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,10,18,20,22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,10,18,22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>0519</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/04</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 1, 2, 4, 6, 10, 18, 20, 22 and 25 are currently pending in the instant application.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-4, 6, 10, 18, 20, 22 and 25 in the paper filed 22 March 2004 and the further election of the compound as found on page 8 of the remarks is acknowledged. An interview with Francis Ginah on 18 May 2004 amended the election of the compound on page 8 of the remarks for the value of R1 to be (CH₂)₂ph.

The elected invention for search and examination is the products of the formula (I) as found in claim 1 wherein:

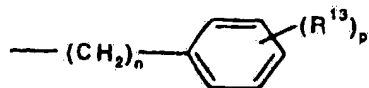
R1 is the group -(L1)-R11,

-(L1) is an alkylene chain of 1 to 8 carbon atoms,

R11 is -(CH₂)_m-R12,

m is an integer from 1 to 6,

R12 is the group



n is an integer from 0 to 2,

R13 is selected from C1 to C8 alkyl,

p is an integer from 0 to 2,

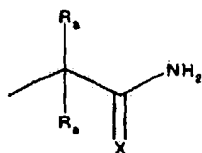
R2 is hydrogen or C1-C4 alkyl,

R3 is -(L3)-Z,

Art Unit: 1626

-(L3) is a bond,

Z is

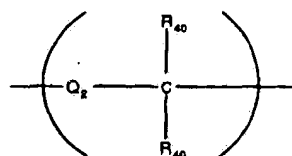


R_a is selected from hydrogen, C2-C8alkyl, aryl, C1-8 alkaryl, C1-C8 alkoxy, aralkyl and -CN,

X is oxygen,

R₄ is -(Lh)-(hydroxyfunctional amide),

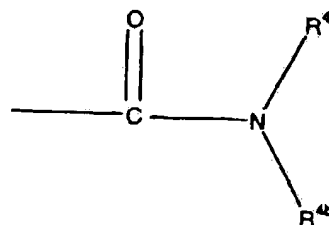
-(Lh)- is represented by the formula



Q₂ is -O-,

R₄₀ is independently selected from hydrogen and C1-C8 alkyl,

(hydroxyfunctional amide) is the group



R_{4a} is -OH,

R_{4b} is selected from the group consisting of H and C1-C8 alkyl,

R₅ is hydrogen and

R₆ and R₇ are independently selected from hydrogen, C1-C6-alkyl, C2-C6 alkenyl and C2-C6 alkynyl and the compounds of claim 20.

The remaining subject matter of claims 1, 2, 4, 10, 18, 22 and 25 that is not drawn to the above elected invention and the subject matter of claim 6 stands

withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. These withdrawn products are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

The requirement is still deemed proper and is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 10, 18, 22 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1 does not provide a definition to the variables m and R12 (and R13, n and p, which are within the definitions of R12 that has not been provided within the claim, see pages 18 and 19 of the instant specification). The claim is therefore indefinite because it is unclear what variables fall within the definitions of m and R12. This rejection can be overcome by amending claim 1 to include the values of m and R12 from the elected invention identified supra.

Claim 2 recites the limitation "C2-C4 alkenyl, -O-(C1-C3 alkyl), -S-(C1-C3 alkyl), and C3-C4 cycloalkyl" in the value of R2 of the compound of claim 1. There is insufficient antecedent basis for this limitation in the claim since the value of R2 in claim 1 can only be hydrogen or C1-C4alkyl. This rejection can be overcome by canceling claim 2.

Claim 4 recites the limitation "where R41, R41, R42 and R43 are each independently selected from hydrogen, C1-C8 alkyl" in the -(Lh)- group of the R4 substituent defined in the claim. There is insufficient antecedent basis for this limitation in the claim since the -(Lh)- definitions in claim 4 do not include the variables R40, R41, R42 or R43. This rejection can be overcome by deleting "where R41, R41, R42 and R43 are each independently selected from hydrogen, C1-C8 alkyl" from claim 4.

Claim 18 recites the limitation "wherein R4 is the group, -(Lc)-(hydroxyfunctional amide group)" in the compound of claim 1. There is insufficient antecedent basis for this limitation in the claim since in claim 1 the definition of R4 is -(Lh)-(hydroxyfunctional amide). This rejection can be overcome by amending -(Lc)- in claim 18 to be -(Lh)-.

Claim Objections

Claims 1, 2, 4, 10, 18, 22 and 25 are objected to as containing non-elected subject matter. Claims 1, 2, 4, 10, 18, 22 and 25 drawn solely to the elected invention identified supra and free of the 35 USC 112 2nd paragraph rejections supra would appear allowable over the prior art of record.

Allowable Subject Matter

Claim 20 appears allowable over the prior art of record.

The closest prior art of record is EP 0 620 215 which discloses sPLA2 inhibitors of the formula (I) which differs from the instant elected invention at the position equivalent to applicants R4. The prior art does not disclose an amino nitrogen substituted directly with a hydroxyl group in the definition of possible substituents at the position equivalent to applicants R4 and fails to provide motivation to prepare the

Art Unit: 1626

instantly claime hydroxy functional amide substituted indole compounds as instantly claimed.


Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600



Joseph McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600